

REMARKS

In the Office Action mailed March 17, 2008 from the United States Patent and Trademark Office, the Examiner rejected claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Kelly (US 6,340,703) in view of Chang et al. (US 2006/00996900 A1) in view of Davis (US 5,708,038) in view of Elkins, R. (1998) in view of Flockhart et al. (WO 9307901 A1).

Rejections under 35 U.S.C. § 102(b) and 103(a):

M.P.E.P. § 2141 sets forth the *Graham* factual enquiries that should be considered when making an obviousness rejection under Section 103: 1) ascertaining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. (Citing *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966).) In addition, M.P.E.P. §§ 2141 and 2142 set forth that “the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.” (Citing *KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. ___, 82 USPQ2d 1385 (2007).)

The M.P.E.P. provides several examples of rationales that can support a rejection under 35 U.S.C. § 103, namely:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try” - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to

combine prior art reference teachings to arrive at the claimed invention.

(M.P.E.P. §§ 2141 & 2143, emphasis added.) As may be seen from the emphasized portions of the above potential rationales, each rationale is dependent on showing known
5 elements from the prior art corresponding to the limitations of the claimed invention.

Therefore, for a rejection under Section 103 to stand, it must explicitly set forth 1) factual findings showing that each claim element was known in the art at the time of the invention, and 2) factual findings showing that one of ordinary skill in the art, at the time of the invention, would have found it obvious to modify or combine the teachings to
10 arrive at the claimed invention. (See, for example, the enumerated required articulations set forth in M.P.E.P. § 2143 for each lettered rationale.)

Note that M.P.E.P. sections 2141 and 2142 set forth that the key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious; rejections on obviousness cannot be sustained by
15 mere conclusory statements. (Citing *KSR*, 82 USPQ2d at 1396 & *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).) Thus, a rejection under Section 103 cannot stand if it contains a mere statement that the claimed invention would have been obvious without explicitly enumerating the necessary factual findings.

Applicant respectfully submits that the references in the Office Action, either
20 alone or in combination, do not teach or suggest all the limitations claimed in the claim set provided herein. Applicant also respectfully submits that the Office Action has failed to show how one of skill in the art would have found it obvious to overcome the differences between the prior art and the claimed invention to arrive at the claimed invention.

The pending Action indicates that one of ordinary skill in the art would have been motivated to combine rutin and quercetin as well as a *Morinda citrifolia* leaf extract for inhibiting estrogen production and providing estrogenic effects, and that it would have been obvious to one of ordinary skill in the art to discover the optimum or workable ranges involving only routine skills in the art. However, the claimed invention involves
30 ranges, which produce unexpected results. In particular the process for utilizing a leaf

extract according to the claims of the present invention have produced unexpected estrogenic affects, when viewed against the background of prior art which teaches that administration of whole foodstuffs containing isoflavones have shown no consistent effect and that plant sterols have been estimated to be approximately 1/400 of that recorded for estradiol.

In contrast, as illustrated in the examples of the present application, administration of a leaf extract according to the claims of the present invention produced an estrogenic effect nearly $\frac{1}{2}$ as potent as that shown by estradiol. Accordingly, the inventive processing methods utilized, and administration of the claimed invention, have produced unexpected estrogenic effects when taken in view of the prior art. Further, the administration of a product as claimed produced the unexpected effect that at higher concentrations administration of *Morinda citrifolia* leaf extract caused inhibition of enzyme induction as noted on page 23 of the originally filed specification. In this non-limiting example, the *Morinda citrifolia* leaf extract exerted a significant induction of alkaline phosphatase, and maximum effect was achieved at 0.3 ml/ml (representing 30 mg dry leaves/ml); higher concentrations caused an inhibition of enzyme induction. The unexpected result that increased concentrations of *Morinda citrifolia* leaf extracts result in an inhibition of enzyme induction is not taught in the cited references.

Kelly indicates that “[c]linical and other studies done to date in this area are highly equivocal, with no consistent effect reported. ...Even when a positive clinical effect has been obtained, it has been with a mixture of a plurality of isoflavones, as well as a wide range of other unidentified dietary components and other biologically active components.” Kelly, Column 3, lines 21-38. Accordingly, Kelly indicates that producing a consistent estrogenic effect by administration of isolated biologically active compounds was beyond the reach of one skilled in the art, and that the interplay between various compounds was sufficiently complicated so as to obfuscate from one skilled in the art which combinations of compounds would effectively act to produce the desired estrogenic effect. Kelly likewise fails to disclose the claimed ranges of quercetin and rutin, and fails to teach or fairly suggest the unexpected result that higher concentrations of leaf extract result in inhibition of enzyme induction.

Chang discloses only that rutin is a flavanoid glycoside comprised of quercetin and a sugar, rutinose, and that many beneficial health effects of rutin have been demonstrated. Chang fails to disclose the claimed ranges of rutin and quercetin, and fails to teach the unexpected result that higher concentrations cause an inhibition of enzyme induction. And Chang's disclosure certainly does not provide insight that would have allowed one skilled in the art to solve the problem posed by Kelly, that administration of biologically active components had failed to produced consistent desirable estrogenic effects.

Kelly's concern with equivocal results is compounded by Davis' assertion, that even when effective, plant sterols produce only a mild estrogenic effect. Davis discloses that estrogens have been isolated from a number of plant sources and that to date, only three sterols having mild estrogenic activity have been isolated. Importantly, Davis teaches that the estrogenic activity of plant sterols has been estimated to be approximately 1/400 of that recorded for estrodile. Accordingly, not only does Davis fail to disclose the claimed ranges of quercetin and rutin, and the unexpected result that higher concentrations cause inhibition of enzyme induction, but Davis additionally teaches away from the use of plant sterols in favor of estrodile, as the plants produce only a mild estrogenic effect, approximately 1/400 of that recorded for estrodile.

Elkins teaches only that *Morinda citrifolia* leaves contain beta-sitosterol. Elkins does little to solve the problem disclosed in Kelly and Davis of equivocal results which provide minimal estrogenic effect.


The magnitude of the unexpected result, as indicated in the table on page 23 of the present invention, is therefore significant and non-obvious in light of the art cited. Accordingly, Applicant respectfully submits the claims provided herein, are not anticipated or rendered obvious by the cited references. Verdegall Bros. v. Union Oil Co. of California, 814 F. 2d 628, 631 (Fed. Cir. 1987).

CONCLUSION

Applicant submits that the amendments made herein do not add new matter and that the claims are now in condition for allowance. Accordingly, Applicant requests favorable reconsideration. If the Examiner has any questions or concerns regarding this communication, the Examiner is invited to call the undersigned.

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Respectfully submitted,


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